REMARKS

After entry of this amendment, claims 1-27 are pending, of which claims 8-17 and 23-25 are withdrawn. The claims have been amended without prejudice or disclaimer to correct antecedent basis, to better comply with U.S. practice, and to address various points made in the Office Action, and find support *inter alia* in the original claims. Claim 1 finds further support in the specification at page 3, lines 19-22. New claims 26 and 27 have been added and find support *inter alia* in the original claim 1. No new matter has been added.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

Claims 1-7 and 18-22 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims have been amended without prejudice or disclaimer to address various points made in the Office Action. In light of the present amendment, it is believed that the majority of the rejections are rendered moot.

Claim 6 is further rejected as being indefinite in denoting certain parenthetical DSM numbers that are not found in the DSMZ catalogue on line.[1] Applicants respectfully disagree.

Applicants note initially that the DSM numbers recited in claim 6, namely DSM 20207, 2649, 20074, 20017, and 4864, are freely available to the public from the German Collection of Microorganisms and Cell Cultures (also known as "Deutsche Sammlung von Mikroorganismen und Zellkulturen" or "DSM"), as evidenced by the attached printout records obtained from the DSM website. The DSM numbers recited in parenthesis, i.e. DSM 15755, 15751, 15754, 15753, and 15752, are the DSM numbers that were originally assigned to the respective strains at the initial deposit. After filing of a patent application, these microorganism strains were re-deposited with the German Collection of Microorganisms and Cell Cultures on July 11, 2003 in order to comply with the regulations of the Budapest Treaty. See Specification at 38, lines 15-17. As a result, new accession numbers were assigned to these strains to replace the initial accession numbers. A summary of the relationship between the DSM numbers assigned to these strains upon the re-deposit and their corresponding initial DSM number is provided in the table at page 39 of the specification. As further support, copies of the corresponding receipts of

[1] According to the Office Action, this rejection is made to claim 1. However, because DSM numbers are found only in claim 6, it is believed that the rejection should be directed to claim 6 instead.

deposit issued by the German Collection of Microorganisms and Cell Cultures showing the identity of the strains denoted by each pair of accession numbers as well as the viability of the deposited strained are also attached with this response. In view of the specification and further in view of the deposits that have been made, Applicants believe that this rejection is rendered moot.

Claims 1-7 and 18-22 are further rejected as being incomplete because of the lack of a "clear recovery step for the product produced." The Examiner acknowledges that no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition. The Examiner, however, asserts that "it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered." Office Action at page 3. Applicants respectfully disagree.

As disclosed in the specification at page 1, lines 4-5, and repeated in the claims, the present application relates to a method for the microbiological isomerization of alpha-hydroxycarboxylic acids. Removing or isolating the desired stereoisomer produced by the claimed method from the reaction medium is described only as one of the numerous preferred embodiments. See page 3, lines 29-34. Similarly, recovering the product prepared by the claimed process is also described as one embodiment that can be done by coupling the claimed method with extraction or distillation. See page 24, lines 13-15. Thus, Applicants respectfully submit that a recovery step is not an essential element of the claimed method and requiring inclusion of such a step in the claims will unduly limit the scope of the claims.

In light of the present amendment and the above remarks, reconsideration and withdrawal of the rejections is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claim 6 is rejected under 35 USC § 112, first paragraph, for lack of enablement due to the specific strains of *L. paracasei*, *L. delbrueckii*, *L. sakei*, and *L. oris* that are used in the claimed method. The Examiner notes that, although a deposit of these strains seems to have been made, the Examiner questions whether the deposit so made meets all the criteria set forth in 37 CFR §§ 1.801-1.809.

As discussed above and stated in the specification at page 38, lines 15-17, the strains recited in claim 6 were made publicly available under the Budapest Treaty on July 11, 2003. Accordingly, it is respectfully submitted that the present application complies with the requirements under 35 U.S.C. § 112. Reconsideration and withdrawal of the rejection is requested.

Claim Rejections – 35 U.S.C. § 102

35 U.S.C. § 102(a) rejection

Claims 1-2 and 7 are rejected under 35 U.S.C. § 102(a) as being anticipated by Glück *et al.* Applicants respectfully submit herewith a declaration by Professor Vilim Simanek, the editor of the Journal "Chemické Listy" published by the Czech Chemical Society in Prague, under 37 C.F.R. § 1.132 for the Examiner's consideration. According to the declaration, the poster presentation by Glück *et al*, P121, as well as the Abstract thereof published in the Journal of Chemické Listy (i.e. the cited Glück reference), was published on **June 28, 2003**, the first day of the International Conference BIOTRANS 2003 at Olomouc, where the poster was presented. Because the present application claims foreign priority to the German application No. 13027582.7 filed on **June 18, 2003**, which is **prior** to the publication date of the cited Glück reference, it is respectfully submitted that the Glück reference is not a prior art against this application under 35 U.S.C. § 102(a).

35 U.S.C. § 102(b) rejection

Claims 1-2 and 7 are rejected under 35 U.S.C. § 102(b) as being anticipated by Felfer *et al.* (hereinafter "Felfer") or Schnell *et al.* (hereinafter "Schnell"). Claims 1-2 are further rejected as being anticipated by Dennis *et al.* (hereinafter "Dennis"). Additionally, claims 1-5 are rejected as being anticipated by Hiyama *et al.* (hereinafter "Hiyama") and claims 1-6 are rejected as being anticipated by Stetter *et al.* (hereinafter "Stetter") in light of DSMZ catalogue. The Examiner alleges that the claims are directed to the microbiological isomerization of alpha-hydroxycarboxylic acids using a racemase, which is taught in all of the cited references. Applicants respectfully disagree and traverse the rejections.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros., Inc. v.*

Union Oil Co., 814 F.2d 628, 631 (Fed. Cir. 1987). "[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference." *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir. 1997).

Felfer discloses the substrate spectrum of a mandelate racemase, which is classified as **[EC 5.1.2.2]**. See Felfer at page 213, left Col., Introduction. In contrast, the racemase used in the claimed method is a lactate racemase, which is classified as **E.C.5.1.2.1**. See Specification at page 3, line 19. Because different class of enzyme is used in the cited reference, Felfer does not anticipate the claims.

Schnell provides a review on enzymatic racemisation and its application to synthetic biotransformations. See Title. Similar to Felfer, the focus of Schnell is primarily on mandelate racemase. Where lactate racemase is discussed (pages 656-657), Schnell states that (1) **lactic acid is the only known substrate** of lactate racemase (page 656, subsection 2.2), and (2) the substrate tolerance of lactate racemase is unknown (page 656, subsection 2.2.1). Thus, Schnell does not teach that the compounds as recited in the claims could be the substrates of lactate racemase. Because Schnell does not teach the isomerization step of the claimed method, Schnell does not anticipate the claims.

Likewise, Dennis discloses lactic acid racemization and proposes a racemization mechanism for racemase obtained from *Cl. Butylicum* as illustrated in Figure 2 at page 873. The Examiner interprets Dennis as teaching the microorganism isomerization of alpha-hydroxycarboxylic acids and points to page 873 for support. However, Applicants submit that the only substrate that is positively identified in Dennis is lactic acid. Furthermore, a fair reading of Dennis at page 873 does not support the Examiner's assertion. Thus, Dennis does not teach that the compounds as recited in the claims could be the substrates of lactate racemase. Because Dennis does not teach the isomerization step of the claimed method, Dennis does not anticipate the claims.

Hiyama discloses the purification and properties of lactate racemase from *Lactobacillus sake*. See Title. The Examiner interprets Hiyama as teaching the microorganism isomerization of alpha-hydroxycarboxylic acids and points to page 106 for support. However, Applicants

submit that, similar to Dennis, Hiyama teaches only the isomerization of **lactic acid** by lactate racemase. Again, a fair reading of Hiyama at page 106 does not support the Examiner's assertion. Thus, Hiyama does not teach that the compounds as recited in the claims could be the substrates of lactate racemase. Because Hiyama does not teach the isomerization step of the claimed method, Hiyama does not anticipate the claims.

Stetter discloses formation of DL-lactic acid by *Lactobacilli* and characterization of a lactic acid racemase from several streptobacteria. See English translation of Title at page 221. The Examiner alleges that Stetter teaches the microorganism isomerization of alpha-hydroxycarboxylic acids using a racemase from various *Lactobacillus* strains, one of which is DSM 20017. Office Action at page 7. However, Applicants submit that, similar to Dennis and Hiyama, Stetter teaches only the isomerization of **lactic acid** by lactate racemase. Thus, Stetter does not teach that the compounds as recited in the claims could be the substrates of lactate racemase. Because Stetter does not teach the isomerization step of the claimed method, Stetter does not anticipate the claims.

In sum, because none of Felfer, Schnell, Dennis, Hiyama, and Stetter, teaches the isomerization step of the claimed method, none of these references anticipates the claims. Reconsideration and withdrawal of the rejections is respectfully requested.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-7 and 18-22 are further rejected under 35 USC § 103(a) as being obvious over Felfer, taken with Hiyama, Stetter, DSMZ catalogue, Mori et al. (hereinafter "Mori") and Seufer-Wasserthal *et al.* (hereinafter "Seufer-Wasserthal"). Applicants respectfully disagree.

To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582, 32 USPQ2d 1031, 1034 (Fed. Cir. 1994).

The Examiner relies on Felfer, Hiyama, Stetter, and Mori for teaching a process of treating an alpha-hydroxycarboxylic acid with a racemase. The Examiner further relies on Hiyama and Stetter for teaching the use of *Lactobacillus* strains DSM 20207 and DSM 2017 in such a process, as demonstrated by the DSMZ catalogue. The Examiner acknowledges that further enzymatic or chemical modifications are not recited in these references, but relies on

Mori and Seufer-Wasserthal for such teaching. Applicants respectfully disagree with the Examiner's characterization of the cited references and their combination to support a rejection.

The explanations provided above under the anticipation rejections for Felfer, Hiyama, and Stetter are equally applicable to this rejection and are incorporated herein in their entirety. As discussed above, none of Felfer, Hiyama, and Stetter teach isomerization of alpha-hydroxycarboxylic acids using a lactate racemase. Furthermore, none of Felfer, Hiyama, and Stetter suggests that the compounds as recited in the claims can be used as substrates of the lactate racemase.

Similarly, Mori does not teach a process of treating an alpha-hydroxycarboxylic acid with a racemase as alleged by the Examiner. Mori discloses a process for producing D-mandelic acid, which is an alpha-hydroxycarboxylic acid. However, Mori's method requires contacting a racemate of mandelic acid with a culture broth or with cells of a microorganism capable of reducing L-mandelic acid into benzoylformic acid (see claim 1). The reaction mixture is subsequently contacted with a culture broth or with cells of a microorganism capable of converting benzoylformic acid into D-mandelic acid. While Mori's reaction mechanism involves stereoselective oxidases/dehydrogenases, there is no teaching or suggestion that a racemase can be used in the disclosed method.

Seufer-Wasserthal does not remedy the lack of teaching of Felfer, Hiyama, Stetter, and/or Mori. Seufer-Wasserthal discloses enzymatic resolution of asymmetric alcohols by means of vinyl esters of polybasic carboxylic acids. The process uses a **lipase** as catalyst (see claim 1), which is an enzyme that belongs to the enzyme class EC 3.1 and completely different from the enzyme class containing lactate racemase (i.e. EC 5.1). Seufer-Wasserthal does not teach or suggest the use of a racemase. The Examiner relies on Seufer-Wasserthal for further enzymatic or chemical modifications.

Accordingly, because the isomerization step of the claimed method is not taught or suggested by Felfer, Hiyama, Stetter, Mori, and Seufer-Wasserthal, alone or in combination, and because the references can be combined only by hindsight, a *prima facie* case of obviousness has not been established.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a petition for a two-month extension of time to and including December 9, 2008 to respond to the Office Action mailed July 9, 2008 with the required fee payment. No further fees are believed due. If any additional fee is due, the Director is hereby authorized to charge our Deposit Account No. 03-2775, under Order No. 13111-00027 US from which the undersigned is authorized to draw.

Respectfully submitted,

By /s/ Hui-Ju Wu

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Attachments:

1. Printout records of strains DSM 20207, 2649, 20074, 20017, and 4864 from the DSM website.
2. Copies of the corresponding receipts of deposit issued by the German Collection of Microorganisms and Cell Cultures.
3. Declaration by Professor Vilim Simanek.